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10/723,268

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Barb Ariel Cohen

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EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER

GOUGH, TIFFANY MAUREEN

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/723,268 | Applicant(s) COHEN ET AL. | |
| | Examiner TIFFANY M. GOUGH | Art Unit 1657 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) 1-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/4/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed 2/27/2008 has been received and entered into the case.

Claims 1-95 are pending, claims 1-59 are withdrawn, and claims 60-95 have been considered on the merits. All arguments and amendments have been fully considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60,67,75,86 and therefore their dependent claims (61-66,68-74,76-85,87-95) **are/stand** rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims recite a method for separating semen into two components, specifically X and Y determining sperm. The separating step is performed in a window of time determined by locating a maximum in a curve obtained by plotting female cells determined by FISH against Koo positive cells, i.e. male cells, and determining a time at which the maximum percent of female cells occurs, further

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the separation step is begun one hour before this “maximum” time for female cells.

Thus, the claims encompass separating a sample in a desired window of time to achieve a maximum of female cells, which has been determined by FISH, for which no written description has been provided. It is not described in the specification how one sample to be separated into two components can differ in the amount of female vs. male cells over time and how a maximum time is determined, and how that maximum time is particularly determined, further, applicant merely analyzes the **already** separated samples at different temperatures and time in examples 1 and 2 by FISH. Thus, it appears as if the FISH analysis is merely a measure of time and temperature compared to the staining process, i.e, the optimum time and temperature at which the ICC positive cells are stained, not a determination of when more female sperm exist in a sample. Applicant appears to be claiming using the FISH analysis to track when more female sperm cells are present in a single sample, for which there is no scientific support or description is provided. Moreover, the examples provided do not support such as determination nor a method of analyzing the percent female cells before the separation step. Because the claims encompass a determination method neither contemplated nor disclosed by the as-filed disclosure, it is clear that applicant was not in possession of the full scope of the claimed subject matter at the time of filing.

Claims 60,67,75,86 and therefore their dependent claims (61-66,68-74,76-85,87-95) **are/stand** rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, as discussed above with respect to the issue of written description, the claims recite methods for separating semen into two components, specifically X and Y determining sperm. The separating step is performed in a window of time determined by locating a maximum in a curve obtained by plotting female cells determined by FISH against Koo positive cells, i.e. male cells, and determining a time at which the maximum percent of female cells occurs, further the separation step is begun one hour before this "maximum" time for female cells and further claim a method of separating into preferred and non preferred sex type, not indicating which sex is preferred. Thus, the claims encompass separating a sample in a desired window of time to achieve a maximum of female cells, which has been determined by FISH, and a method of obtaining either a preferred sample of male or female sperm, for which no scientific support has been provided. It is not described in the specification how one sample to be separated into two components can differ in the amount of female vs. male cells over time and how that maximum time is particularly determined, further, applicant merely analyzes the **already** separated samples at different temperatures and time in examples 1 and 2 by FISH. Thus, it appears as if the FISH analysis is merely a measure of time and temperature compared to the staining process, i.e, the optimum time and temperature at which the ICC positive cells are stained, not a determination of when more female sperm exist in a sample. Applicant appears to be claiming using the FISH analysis to track when more female sperm cells are present in a single sample, for which there is no scientific support or description is provided. Moreover, the examples provided do not

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support such as determination nor a method of analyzing the percent female cells before the separation step. Thus, in view of the lack of any specific guidance with respect to how a maximum amount of female sperm occurs at a specific time point in one sample, one skilled in the art would expect a trial and error process to determine how such an occurrence is possible with respect to a sample and how determining such would apply to the as disclosed application, and would further have to determine through undue experimentation, without guidance from the specification, how to obtain a window of time when a maximum amount of female sperm exist in a sample.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary to determine how and when a maximum amount of female sperm occur in a sample in relation to the Y sperm in the sample, limited amount of guidance and limited number of working examples in the specification on how the amount of female cells present in a sample change over time; nature of the invention; state of the prior art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Further, applicants specification, examples, Tables, etc only practice the invention with the female cells being the preferred sex type, not at all enabling one to obtain a preferred **male** sample. Moreover, the examples provided do not support obtaining a preferred male sex type in applicants claimed method. Thus, in view of the lack of any specific guidance with respect to how to obtain a male preferred sex type using applicant method, one skilled in the art would expect a trial and error process to determine how such a preference can be analyzed using such method and how

determining such would apply to the as disclosed application, and would further have to determine through undue experimentation, without guidance from the specification, how to obtain a male population using the steps and methods of the invention.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary to determine how and when a maximum amount of male sperm occur in a sample in relation to the X sperm in the sample, limited amount of guidance and limited number of working examples in the specification on how the amount of male cells present in a sample change over time; nature of the invention; state of the prior art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Response to Arguments

Applicant's arguments filed 2/27/2008 have been fully considered but they are not persuasive. Applicant argues that the specification, figures, examples provide adequate support of applicants invention, however example 2 does not provide reproducibility of applicants invention. There is no such showing of reproducibility of applicants "window of time." In fact, there is nothing to indicate any time or sex outcome, merely if the sperm samples are motile after freezing, clearly, Table 5 does not show any data suggesting reproducibility of applicant's claimed window of time. Further, it is unclear how applicants Koo positive cells corresponds to the % female cells, Fig. 1-4 plot female vs. % Koo positive, which does not indicate the significance. Should applicant consider a Koo positive cell to be a female cell, then applicant would be plotting female vs. female, not establishing clear evidence of

applicant's invention. Further, as indicated above, applicant figures are not clearly labeled.

In applicant's response p.18, it is stated that applicant shows that "...amounts of female vs. male cells differ over time in a **separated** sample", however, applicant **does not** appear to show **separation at different times**. Applicant's definition, according to the examples, of **separated samples** appears to be taking aliquots from a semen sample at different time points. This is not consistent with definition known by those in the art. Semen separation based on sex to obtain a sample comprising more of a preferred sex type is known in the art as actual separating of the male from the female cells. Applicant has not provided **separated** samples having a higher number of sperm of a preferred type than that of nonpreferred. It has been interpreted that applicant has actually taken aliquots of a sperm sample, incubated at different temperatures for a period of time and analyzed the amount of X and Y cells in the sample with regards to temperature and amount of time at that specific temperature **BEFORE** separation. Thus, applicant has not demonstrated that they had full possession of the claimed subject matter at time of filing. Applicant's argument is not persuasive.

Applicant states that they are using FISH to determine a time period during which there is a maximum of female cells in a sample. The method of using FISH to determine X and Y sexed sperm in a sample is well known in the art. Further on pg.5 of applicant specification and in claim 60, they state, "plotting percent female cells determined by FISH against percent Koo positive cells...", thus FISH as claimed and provided in the specification, is merely used to determine percent female cells and then

the female cells are plotted against Koo positive cells, at which a time period is then observed. Applicant's argument is not persuasive.

Applicant argues that it is not required to analyze the percent female cells before the separation step. However, as claimed and as disclosed, the nature of the invention **is** analysis before a separation step to ensure obtaining a desired sex type, thus applicants argument is not persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 60,67,75,86 and therefore their dependent claims (61-66,68-74,76-85,87-95) **are/stand** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, it is indefinite from where applicant is plotting the maximum percentage of female cell occurrence, it is not clear how a sperm sample can particularly produce more female than male determining sperm at a specific time in the sample. Further it is unclear what "the curve" is referring to and how the window of time is determined with regards to information obtained by FISH. It is also unclear whether applicant is separating/sorting by FISH or by a different separation method and whether or not FISH is necessarily required in the method, the use of FISH is not a positive step within the method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 60,61,63,75 are/stand rejected under 35 U.S.C. 102(b) as being anticipated by Sills et al (American Journal of Reproductive Immunology, vol. 40, 1998).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60,61,63,75.

Sills et al teach labeling human sperm with IgM antibodies against H-Y antigen, incubating the sample with IgM antibody affixed to paramagnetic beads, i.e, cell binding agents, and further separating the sperm cells into two populations. The X and Y chromosome frequencies in the two populations were assayed by FISH (see METHOD OF STUDY section in abstract). Sills et al teach incubating the sperm sample at 4°C and then separating using antibody labeled beads.

Thus, the reference anticipates the claimed subject matter.

Response to Arguments

Applicant's arguments filed 2/27/2008 have been fully considered but they are not persuasive. First, applicant argues that Sills fails to teach or suggest the method claimed by applicant, specifically, treating semen to obtain a preferred sex type. However, Sills clearly teaches a method of treating semen for sex selection. Secondly, applicant argues that the art does not teach obtaining two components wherein one has a higher number of a preferred sex type. While this is not exactly stated in the art, it does suggest using such method to achieve a desired family structure and suggest significant enrichment of sex-chromosome specific sperm (see p.44, 3rd full paragraph). Third, applicant argues that the art does not teach or suggest performing in a window of time. Applicant only claims performing in a window of time, not what the window of time is or from when the window of time starts. The method as claimed does not actually require that the window be determined by located a maximum in a curve, merely that it **can be**, clearly not required by the method. Sills does teach separating in a window of time specifically 1-2 hours after ejaculation, and analyzing by FISH. Thus, the reference is anticipatory.

Claims 60-62,67-69,82-83,86-91,93 are/stand rejected under 35 U.S.C. 102(b) as being anticipated by Benjamin (6153373).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-62,67-69,75-80,82-83,86-91,93. Specifically applicant claims using a cell binding agent, i.e. beads, to separate the

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sperm cells to obtain a desired sex type sperm. The separated sperm are used for fertilization/insemination in mammals.

Benjamin (6153373) et al teach a method of increasing the percentage of mammalian offspring of either sex by contacting a sperm sample with an antibody specific to a selected spermatozoa type, i.e. cell binding agent, which is bound to magnetic beads of diameter from 0.1 to 2 microns and subsequently collecting sperm of only a X or Y determinative type (see abstract and col.1 and 2). They teach a separation method from mammals such as livestock including cattle, sheep, and pigs, as well as horses, dogs, cats and humans (col. 2, lines 19-29). The separation method provides insemination with a sperm sample enriched in X or Y sperm which are useful in artificial insemination methods (col. 1, lines 55-65). They teach separating the sperm to produce X and /or Y subpopulations containing 80-90% of the desired X or Y sperm (col. 2, lines 30-50). Benjamin et al teach labeling the sperm with antibodies which bind to the X or Y specific proteins from sperm cells. They specifically teach the use of antibodies which are specific for and bind to Y sperm such as those which bind to the H-Y antigen, i.e. Koo positive cells (see col. 3).

Thus , the reference anticipates the claimed subject matter.

Claims 60-62,67-69,82-83,86-91,93 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Benjamin (US2003/0068654A1).

Benjamin (US2003/0068654A1) and) et al teach a method of increasing the percentage of mammalian offspring of either sex by contacting a sperm sample with an

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antibody specific to a selected spermatozoa type, i.e. cell binding agent, which is bound to magnetic beads of diameter from 0.1 to 2 microns and subsequently collecting sperm of only a X or Y determinative type (0012,0013,0022). They teach a separation method from mammals such as livestock including cattle, sheep, and pigs, as well as horses, dogs, cats and humans (0015). The separation method provides insemination with a sperm sample enriched in X or Y sperm which are useful in artificial insemination methods (0011 and 0015). They teach separating the sperm to produce X and /or Y subpopulations containing 80-90% of the desired X or Y sperm (0016). Benjamin et al teach labeling the sperm with antibodies which bind to the X or Y specific proteins from sperm cells. They specifically teach the use of antibodies which are specific for and bind to Y sperm such as those which bind to the H-Y antigen, i.e. Koo positive cells (0020).

Thus , the reference anticipates the claimed subject matter.

Claims 60-62,67-69,82-83,86-91,93 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Benjamin (6489092).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-62,67-69,75-80,82-83,86-91,93. Specifically applicant claims using a cell binding agent, i.e. beads, to separate the sperm cells to obtain a desired sex type sperm. The separated sperm are used for fertilization/insemination in mammals.

Benjamin (6489092) et al teach a method of increasing the percentage of mammalian offspring of either sex by contacting a sperm sample with an antibody

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specific to a selected spermatozoa type, i.e. cell binding agent, which is bound to magnetic beads of diameter from 0.1 to 2 microns and subsequently collecting sperm of only a X or Y determinative type (abstract and col. 2, lines 15-21). They teach a separation method from mammals such as livestock including cattle, sheep, and pigs, as well as horses, dogs, cats and humans (col.2, lines 25-36). The separation method provides insemination with a sperm sample enriched in X or Y sperm which are useful in artificial insemination methods (col.2-3). They teach separating the sperm to produce X and /or Y subpopulations containing 80-90% of the desired X or Y sperm (col.2, lines 36-55). Benjamin et al teach labeling the sperm with antibodies which bind to the X or Y specific proteins from sperm cells. They specifically teach the use of antibodies which are specific for and bind to Y sperm such as those which bind to the H-Y antigen, i.e. Koo positive cells (col.3).

Thus , the reference anticipates the claimed subject matter.

Response to Arguments

Applicant's arguments filed 2/27/2008 have been fully considered but they are not persuasive. Applicant argues that Benjamin(s) fails to teach or suggest determining a window of time after ejaculation for performing a separation step to increase the percentage of offspring. Applicant does not claim a window of time **after ejaculation**, only a window of time which is indefinite and not clear as to when the window of time actually starts, thus Benjamin does perform such a method in a window of time (see example 1). The method as claimed does not actually require that the window be

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determined by located a maximum in a curve, merely that it **can be**, clearly not required by the method.

Claims 60-63,67-70,75 are/stand rejected under 35 U.S.C. 102(b) as being anticipated by Blecher et al (US2001/0041348 A1).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-63,67-70,75. Specifically applicant claims using a cell binding agent, i.e. beads, to separate the sperm cells to obtain a desired sex type sperm. The separated sperm are used for fertilization/insemination in mammals. Applicant also claims a method step of cooling the semen for separation.

Blecher teach a method of separating semen into male or female determining sperm by treating the sperm with antibodies bound to carriers such as beads, specific for sex-chromosome molecules (0042, 0079,0129-0132). There method may be applied to mammals such as cattle, dogs, cats, horses, pigs, sheep and humans (0067). Blecher teach binding the magnetic beads with either male or female specific antibodies, therefore depending on which sex determining sperm is desired, the separated samples will therefore contain more of one preferred sex type sperm than the other (see example 5 (0166) p. 13). Blecher teach using cryopreserved semen, i.e. cooled sperm for the separation method.

Thus , the reference anticipates the claimed subject matter.

Response to Arguments

Applicant's arguments filed 2/27/2008 have been fully considered but they are not persuasive. Applicant argues that Blecher fails to teach or suggest determining a window of time after ejaculation for performing a separation step to increase the percentage of offspring. Applicant does not claim a window of time **after ejaculation**, only a window of time which is indefinite and not clear as to when the window of time actually starts, thus Blecher does perform such a method in a window of time (see examples). The method as claimed does not actually require that the window be determined by locating a maximum in a curve, merely that it **can be**, clearly not required by the method .

Claims 60-62,67-69,75,82 are/stand rejected under 35 U.S.C. 102(b) as being anticipated by Zavos et al (4999283).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-62, 67-69, 75, 82. Specifically applicant claims using a cell binding agent, i.e. beads, to separate the sperm cells to obtain a desired sex type sperm. The separated sperm are used for fertilization/insemination in mammals.

Zavos teach a method of separating male and female determining spermatozoa and further increasing the probability of producing offspring of either sex (col. 3, lines 3-20) by exposing the sperm to an antibody which specifically binds with the Y sperm through the H-Y surface antigen, i.e. a Koo positive cell, and a second antibody bound

to beads which then binds to the Y specific sperm. The female spermatozoa are then recovered and while the male sperm remain bound to the beads. If desired, the male sperm can be further recovered from the beads (col.3, lines 20-50). Zavos teach the sperm to be used for artificial insemination (col. 8, lines 47-50).

Thus, the reference anticipates the claimed subject matter.

Response to Arguments

Applicant's arguments filed 2/27/2008 have been fully considered but they are not persuasive. Applicant argues that Blecher fails to teach or suggest determining a window of time after ejaculation for performing a separation step to increase the percentage of offspring. Applicant does not claim a window of time **after ejaculation**, only a window of time which is indefinite and not clear as to when the window of time actually starts, thus Blecher does perform such a method in a window of time (see examples). The method as claimed does not actually require that the window be determined by located a maximum in a curve, merely that it **can be**, clearly not required by the method .

Claims 60-62,67-69,73,74 are rejected under 35 U.S.C. 102(b) as being anticipated by Van den Bovenkamp (3687806).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-62,67-69,75,82. Specifically applicant claims using a cell binding agent to separate the sperm cells to obtain a desired sex

type sperm. The separated sperm are used for fertilization/insemination in mammals to obtain a specific ratio of female versus male offspring.

Van den Bovenkamp teaches a method for controlling the sex of mammalian offspring. Van den Bovenkamp teaches separating sperm to provide for a higher number of a preferred sex type, specifically X-type sperm. The sperm are in contact with cell binding agents, antibodies, are fractionated and then separated to give an excess of X-sperm (see col.5 and 6). Bovenkamp also teaches the method to be an advantage in animal husbandry because one would be able to produce only female offspring in cows from such method, i.e., producing twice as many female calves born than male calves (see col. 7, lines 5-19).

Response to Arguments

Applicant's arguments filed 2/27/2008 have been fully considered but they are not persuasive. Applicant argues that Blecher fails to teach or suggest determining a window of time after ejaculation for performing a separation step to increase the percentage of offspring. Applicant does not claim a window of time **after ejaculation**, only a window of time which is indefinite and not clear as to when the window of time actually starts, thus Blecher does perform such a method in a window of time (see examples). The method as claimed does not actually require that the window be determined by locating a maximum in a curve, merely that it **can be**, clearly not required by the method .

Although the above references do not teach performing the separation step in a determined window of time, it is unclear whether or not this step is actually required in the method and lacks any positive steps with regards to applicant's invention. In light of any support from the specification, it is not clear how such a limitation applies to the method of separating in the claims and whether or not this step is necessarily required.

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 60-63,67-70,75-80,82-83,86-91,93 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin (US2003/0068654A1) or Benjamin (6153373) or Benjamin (6489092) in view of Sills et al (AJRI, vol 40, 1998).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-62,67-69,75-80,82-83,86-91,93. Specifically applicant claims using a cell binding agent, i.e. beads, to separate the sperm cells to obtain a desired sex type sperm. The separated sperm are used for fertilization/insemination in mammals. Additionally a method step of using FISH to determine X and Y sperm is suggested in the methods.

Benjamin (US2003/0068654A1,6153373, 6489092) et al teach a method of increasing the percentage of mammalian offspring of either sex by contacting a sperm sample with an antibody specific to a selected spermatozoa type, which is bound to magnetic beads of diameter from 0.1 to 2 microns and subsequently collecting sperm of only a X or Y determinative type (0012,0013,0022). They teach a separation method from mammals such as livestock including cattle, sheep, and pigs, as well as horses, dogs, cats and humans (0015). The separation method provides insemination with a sperm sample enriched in X or Y sperm which are useful in artificial insemination methods (0011 and 0015). They teach separating the sperm to produce X and /or Y subpopulations containing 80-90% of the desired X or Y sperm (0016). Benjamin et al teach labeling the sperm with antibodies which bind to the X or Y specific proteins from sperm cells. They specifically teach the use of antibodies which are specific for and bind to Y sperm such as those which bind to the H-Y antigen, i.e. Koo positive cells (0020).

Benjamin do not teach using FISH in analyzing male versus female sperm in addition to their separation methods nor do they teach cooling the semen before separating.

Sills et al teach labeling human sperm with IgM antibodies against H-Y antigen by paramagnetic beads and were separated into two populations. The X and Y chromosome frequencies in the two populations were assayed by FISH (see METHOD OF STUDY section in abstract). Sills et al teach incubating the sperm sample at 4°C and then separating using antibody labeled beads.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used FISH in analyzing the percentage of male versus female sperm cells in a sample since FISH is known and is used in the art in analyzing and separating female vs. male sperm cells in a sample, as evidenced by Sills et al. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Sills to include FISH analysis in a method of sperm separation with a reasonable expectation of successfully determining the amount X and Y sperm in a separated sample.

It also would have been obvious to one of ordinary skill in the art at the time the invention was made to have cooled the semen before performing the separation step in a method taught by Benjamin, as evidenced by Sills et al, because they teach cooling the semen prior to performing the separation step. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Sills to cool the semen before performing a separation step with a reasonable expectation of

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successfully separating the sperm into X and Y-determining sperm in a separation method of a sample.

Claims 60-63,67-70,75 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Blecher et al (US2001/0041348 A1) in view of Sills et al (AJRI, vol 40, 1998).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-63,67-70,75. Specifically applicant claims using a cell binding agent, i.e. beads, to separate the sperm cells to obtain a desired sex type sperm. The separated sperm are used for fertilization/insemination in mammals. Applicant also claims a method step of cooling the semen for separation and a method step of using FISH to determine X and Y sperm in the methods are suggested.

Blecher et al teach a method of separating semen into male or female determining sperm by treating the sperm with antibodies bound to carriers such as beads, specific for sex-chromosome molecules (0042, 0079,0129-0132). There method may be applied to mammals such as cattle, dogs, cats, horses, pigs, sheep and humans (0067). Teach using cryopreserved semen, i.e. cooled sperm.

Blecher do not teach using FISH in analyzing male versus female sperm in addition to their separation methods nor do they teach cooling the semen before separating.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used FISH in analyzing the percentage of male versus female sperm cells in a sample since FISH is known and is used in the art in analyzing and separating female vs. male sperm cells in a sample, as evidenced by Sills et al. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Sills to include FISH analysis in a method of sperm separation with a reasonable expectation of successfully determining the amount X and Y sperm in a separated sample.

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Claims 60-62,67-69,75,82 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zavos et al (4999283) in view of Sills et al (AJRI, vol 40, 1998).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-62,67-69,75,82. Specifically applicant claims using a cell binding agent, i.e. beads, to separate the sperm cells to obtain a desired sex type sperm. The separated sperm are used for fertilization/insemination in mammals. A method step of using FISH to determine X and Y sperm in the methods are suggested.

Zavos (4999283) et al teach a method of separating male and female determining spermatozoa and further increasing the probability of producing offspring of either sex (col. 3, lines 3-20) by exposing the sperm to an antibody which specifically binds with the Y sperm through the H-Y surface antigen, i.e. a Koo positive cell, and a second antibody bound to beads which then binds to the Y specific sperm. The female spermatozoa are then recovered and while the male sperm remain bound to the beads. If desired, the male sperm can be further recovered from the beads (col.3, lines 20-50).

Zavos do not teach using FISH in analyzing male versus female sperm in addition to their separation methods nor do they teach cooling the semen before separating.

Sills et al teach labeling human sperm with IgM antibodies against H-Y antigen by paramagnetic beads and were separated into two populations. The X and Y chromosome frequencies in the two populations were assayed by FISH (see METHOD

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OF STUDY section in abstract). Sills et al teach incubating the sperm sample at 4°C and then separating using antibody labeled beads.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used FISH in analyzing the percentage of male versus female sperm cells in a sample since FISH is known and is used in the art in analyzing and separating female vs. male sperm cells in a sample, as evidenced by Sills et al. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Sills to include FISH analysis in a method of sperm separation with a reasonable expectation of successfully determining the amount X and Y sperm in a separated sample.

It also would have been obvious to one of ordinary skill in the art at the time the invention was made to have cooled the semen before performing the separation step in a method taught by Zavos, as evidenced by Sills et al, because they teach cooling the semen prior to performing the separation step. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Sills to cool the semen before performing a separation step with a reasonable expectation of successfully separating the sperm into X and Y-determining sperm in a separation method of a sample.

Claims 60-62,67-69,73,74 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Van den Bovenkamp (3687806) in view of Sills et al (AJRI, vol 40, 1998).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-62,67-69,75,82. Specifically applicant claims using a cell binding agent to separate the sperm cells to obtain a desired sex type sperm. The separated sperm are used for fertilization/insemination in mammals to obtain a specific ratio of female versus male offspring. A method step of using FISH to determine X and Y sperm in the methods are suggested.

Van den Bovenkamp teaches a method for controlling the sex of mammalian offspring. Van den Bovenkamp teaches separating sperm to provide for a higher number of a preferred sex type, specifically X-type sperm. The sperm are in contact with cell binding agents, antibodies, are fractionated and then separated to give an excess of X-sperm (see col.5 and 6). Bovenkamp also teaches the method to be an advantage in animal husbandry because one would be able to produce only female offspring in cows from such method, i.e, producing twice as many female calves born than male calves (see col. 7, lines 5-19).

Van den Bovenkamp does not teach using FISH in analyzing male versus female sperm in addition to their separation methods

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.Claims 60-63,67-70,75-80,82-83,86-91,93 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin (US2003/0068654A1) or Benjamin (6153373) or Benjamin (6489092) in view of Johnson (Reprod. Fertil. 1995).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-62,67-69,75-80,82-83,86-91,93.

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Specifically applicant claims using a cell binding agent, i.e. beads, to separate the sperm cells to obtain a desired sex type sperm. The separated sperm are used for fertilization/insemination in mammals. Additionally a method step of using FISH to determine X and Y sperm is suggested in the methods.

Benjamin (US2003/0068654A1, 6153373, 6489092) et al teach a method of increasing the percentage of mammalian offspring of either sex by contacting a sperm sample with an antibody specific to a selected spermatozoa type, which is bound to magnetic beads of diameter from 0.1 to 2 microns and subsequently collecting sperm of only a X or Y determinative type (0012, 0013, 0022). They teach a separation method from mammals such as livestock including cattle, sheep, and pigs, as well as horses, dogs, cats and humans (0015). The separation method provides insemination with a sperm sample enriched in X or Y sperm which are useful in artificial insemination methods (0011 and 0015). They teach separating the sperm to produce X and /or Y subpopulations containing 80-90% of the desired X or Y sperm (0016). Benjamin et al teach labeling the sperm with antibodies which bind to the X or Y specific proteins from sperm cells. They specifically teach the use of antibodies which are specific for and bind to Y sperm such as those which bind to the H-Y antigen, i.e. Koo positive cells (0020).

Benjamin do not teach using FISH in analyzing male versus female sperm in addition to their separation methods.

Johnson (Reprod. Fertil. 1995) teaches using FISH to successfully separate X and Y-chromosome bearing sperm obtaining 90% pure X or Y sperm. Many offspring

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have been produced in mammals, specifically cattle, sheep and pigs which support the predicted sex of the offspring.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used FISH in analyzing the percentage of male versus female sperm cells in a sample since FISH is known and is used in the art in analyzing and separating female vs. male sperm cells in a sample, as evidenced by Johnson. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Johnson to include FISH analysis in a method of sperm separation with a reasonable expectation of successfully determining the amount X and Y sperm in a separated sample.

Claims 60-63,67-70,75 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Blecher et al (US2001/0041348 A1) in view of Johnson (Reprod. Fertil. 1995).

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Blecher et al teach a method of separating semen into male or female determining sperm by treating the sperm with antibodies bound to carriers such as beads, specific for sex-chromosome molecules (0042, 0079,0129-0132). There method may be applied to mammals such as cattle, dogs, cats, horses, pigs, sheep and humans (0067). Teach using cryopreserved semen, i.e. cooled sperm.

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Johnson (Reprod. Fertil. 1995) teaches using FISH to successfully separate X and Y-chromosome bearing sperm obtaining 90% pure X or Y sperm. Many offspring have been produced in mammals, specifically cattle, sheep and pigs which support the predicted sex of the offspring.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used FISH in analyzing the percentage of male versus

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female sperm cells in a sample since FISH is known and is used in the art in analyzing and separating female vs. male sperm cells in a sample, as evidenced by Johnson.

Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Johnson to include FISH analysis in a method of sperm separation with a reasonable expectation of successfully determining the amount X and Y sperm in a separated sample.

Claims 60-62,67-69,73,74,82 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Van den Bovenkamp (3687806) in view of Johnson (Reprod. Fertil. 1995).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-62,67-69,75,82. Specifically applicant claims using a cell binding agent to separate the sperm cells to obtain a desired sex type sperm. The separated sperm are used for fertilization/insemination in mammals to obtain a specific ratio of female versus male offspring. A method step of using FISH to determine X and Y sperm in the methods are suggested.

Van den Bovenkamp teaches a method for controlling the sex of mammalian offspring. Van den Bovenkamp teaches separating sperm to provide for a higher number of a preferred sex type, specifically X-type sperm. The sperm are in contact with cell binding agents, antibodies, are fractionated and then separated to give an excess of X-sperm (see col.5 and 6). Bovenkamp also teaches the method to be an advantage in animal husbandry because one would be able to produce only female offspring in cows

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Van den Bovenkamp does not teach using FISH in analyzing male versus female sperm in addition to their separation methods

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used FISH in analyzing the percentage of male versus female sperm cells in a sample since FISH is known and is used in the art in analyzing and separating female vs. male sperm cells in a sample, as evidenced by Johnson. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Johnson to include FISH analysis in a method of sperm separation with a reasonable expectation of successfully determining the amount X and Y sperm in a separated sample.

Claims 60-72,75-80,82-91,93,94,95 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin (US2003/0068654A1) or Benjamin (6153373) or Benjamin (6489092) in view of Spaulding (5021244).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-62,67-69,75-80,82-83,86-91,93.

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Specifically applicant claims using a cell binding agent, i.e. beads, to separate the sperm cells to obtain a desired sex type sperm. The separated sperm are used for fertilization/insemination in mammals. Additionally a method step of using FISH to determine X and Y sperm is suggested in the methods.

As discussed above Benjamin teaches the methods according to claims 60-62,67-69,82-83,86-91,93 (see above Benjamin 102 rejections).

Benjamin do not teach immediately cooling the semen after collection.

However, Spaulding teach immediately cooling to temperatures of 5°C after collection of the ejaculated sperm (see col. 9, lines 15-35). This sperm sample is then analyzed and sorted by FACS.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have cooled the semen immediately after collection to temperatures of at least 12C as evidenced by Spaulding. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Spaulding to cool the semen immediately after collection, with a reasonable expectation of successfully in obtaining a sample separated by sex because they teach this sample to be useful in FACS, fluorescent analysis and sorting based on sex chromosomes.

Claims 60-70,75,82,84,85 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Blecher et al (US2001/0041348 A1) in view of Spaulding (5021244).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-63,67-70,75. Specifically applicant

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claims using a cell binding agent, i.e. beads, to separate the sperm cells to obtain a desired sex type sperm. The separated sperm are used for fertilization/insemination in mammals. Applicant also claims a method step of cooling the semen for separation and a method step of using FISH to determine X and Y sperm in the methods are suggested.

As discussed above Blecher teaches the methods according to claims 60-63,67-70,75 (see above Blecher 102 rejections).

Blecher do not teach immediately cooling the semen after collection.

However, Spaulding teach immediately cooling to temperatures of 5°C after collection of the ejaculated sperm (see col. 9, lines 15-35). This sperm sample is then analyzed and sorted by FACS.

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Claims 60-72,75,82,84,85 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zavos et al (4999283) in view of Spaulding (5021244).

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As discussed above Zavos teaches the methods according to claims 60-62,67-69,75,82 (see above Zavos 102 rejections).

Zavos do not teach immediately cooling the semen after collection.

However, Spaulding teach immediately cooling to temperatures of 5°C after collection of the ejaculated sperm (see col. 9, lines 15-35). This sperm sample is then analyzed and sorted by FACS.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have cooled the semen immediately after collection to temperatures of at least 12C as evidenced by Spaulding. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Spaulding to cool the semen immediately after collection, with a reasonable expectation of successfully in obtaining a sample separated by sex because they teach this sample to be useful in FACS, fluorescent analysis and sorting based on sex chromosomes.

Claims 60-74 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Van den Bovenkamp (3687806) in view of Spaulding (5021244).

Applicant claims methods of separating semen into two components, X and Y sperm according to the method steps of claims 60-62,67-69,75,82. Specifically applicant claims using a cell binding agent to separate the sperm cells to obtain a desired sex type sperm. The separated sperm are used for fertilization/insemination in mammals to obtain a specific ratio of female versus male offspring. A method step of using FISH to determine X and Y sperm in the methods are suggested.

As discussed above Van den Bovenkamp teaches the methods according to claims 60-62,67-69,73,74 (see above Bovenkamp 102 rejections).

Bovenkamp do not teach immediately cooling the semen after collection.

However, Spaulding teach immediately cooling to temperatures of 5°C after collection of the ejaculated sperm (see col. 9, lines 15-35). This sperm sample is then analyzed and sorted by FACS.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have cooled the semen immediately after collection to temperatures of at least 12C as evidenced by Spaulding. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Spaulding to cool the semen immediately after collection, with a reasonable expectation of successfully in obtaining a sample separated by sex because they teach this sample to be useful in FACS, fluorescent analysis and sorting based on sex chromosomes.

Thus, the invention as a whole is prima facie obvious over the prior art.

Response to Arguments

Applicant's arguments filed 2/27/2008 have been fully considered but they are not persuasive. Applicant argues that none of the combination of references teach or suggest a window of time after ejaculation for performing the separation to obtain the desired increase in the percentage of offspring in either sex. In response to applicant's arguments that there is no motivation or teaching/suggestion of a window of time, applicant is advised that KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*,--USPQ2d--,slip op at 20,(Bd. Pat. App & Interf. June 25, 2007) (citing *KSR*,82 USPQ2d at 1396) (available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>) .

Applicant states that they use FISH with Koo positive cells to determine the time when particular sperm cells are at a maximum. The art of record does teach performing separation, specifically within a time period after ejaculation, to achieve samples of desired increases in offspring of a desired sex. Thus, the references teach separation in a window of time wherein FISH was used to determine the percentage of male and female cells and then to separate accordingly to desire. Thus, it would have been obvious to one of ordinary skill in the art to separate sperm samples into desired sex components as determined by FISH and sex-specific antibodies in a window of time as such methods are known in the art. Further, the method as claimed does not actually require that the window be determined by located a maximum in a curve, merely that it **can be**, clearly not necessarily required by the method.

Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY M. GOUGH whose telephone number is (571)272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tiffany M Gough/
Examiner, Art Unit 1657

/Ruth A. Davis/

Primary Examiner, Art Unit 1651